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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,504	09/26/2003	Thierry Plouvier	CHIESI.001C1	8679

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EXAMINER

HAWES, PILI ASABI

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/672,504	<b>Applicant(s)</b> PLOUVIER ET AL.	
	<b>Examiner</b> Pili A. Hawes	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05-27-2004</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### ***Summary***

Receipt of the Information Disclosure Statement(s) filed 05-27-2004 is acknowledged. Claims 25, 33-59 are withdrawn. Claims 1-32 are pending in this action. Claims 1-32 are rejected.

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-32 in the reply filed on 09-12-2005, is acknowledged.

Claim 25 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claim 33-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09-12-2005.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 17-24, 31 and 32 rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/47134. US patent 6,429,229, which is the 371 of the PCT/FR99/00545, whose published application is WIPO document WO 99/47134, is relied upon as the English translation of WO 99/47134 (WO '134).

WO '134 discloses compositions composed of salts of the formula  $Xn_1, Y, Zn_2$ , where  $n_1, n_2=0$  or 1. Where X represents the amino acids ornithine, arginine, lysine, histidine, or glutamine. Where Y represents a keto acid, such as keto-glutaric acid. Where Z represents a natural amino acid, such as ornithine, arginine, lysine, histidine, or glutamine. The reference further discloses the compositions are prepared for medicinal use, and the active principle is combined with a pharmaceutically acceptable vehicle. The composition of the invention is prepared for oral, parenteral, and rectal use. The composition is used to treat gastrointestinal pathologies.

Claims 1-3, 5-21, 23-32 rejected under 35 U.S.C. 102(b) as being anticipated by Cynober, L., "Ornithine alpha-ketoglutarate in Nutritional Support", Nutrition, (vol. 7, Sept. Oct. 1991, p. 313-322.

Cynober teaches oral composition of ornithine alpha-ketoglutarate (OKG) available and sold in two forms, as a freeze-dried powder for parenteral administration, and as a hydrated salt for oral and enteral administration (p. 314). The hydrated powder is an enteral composition. Powders are made up of a plurality of granules or particles. Therefore the reference anticipates enteric particles and granules. The reference further discloses this composition being given orally with food as a diet supplement for elderly patients (p. 317). Food is a nutritional material that is a pharmaceutically acceptable vehicle that is dilutable or dispersible in aqueous solvents.

#### ***Cited of Interest***

Stern et al. US 5912014, is cited as a teaching that the use of enteric coatings such as EUDRAGIT to coat pharmaceutical compositions for the purpose of stabilizing

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them in acidic environments is known in the art. The reference further teaches ornithine and glutaric acid are pH lowering agents.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 3441650

US 5817329

US 6503506

US 4957938

US 5733884


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P. A. Hawes  
Examiner-1615

  
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